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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/595,101	04/16/2007	Albrecht Weiss	C 2816 PCT/US	2593

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EXAMINER	
HANLEY, SUSAN MARIE	
ART UNIT	PAPER NUMBER
1651	

NOTIFICATION DATE	DELIVERY MODE
11/09/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipdocket@foxrothschild.com

Office Action Summary	Application No.	Applicant(s)	
	10/595,101	WEISS ET AL.	
	Examiner	Art Unit	
	SUSAN HANLEY	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 July 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-44* is/are pending in the application.

4a) Of the above claim(s) *34-37 and 41-44* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20-33 and 38-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *09/19/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 20-44 are pending.

Election/Restrictions

Applicant's election without traverse of Group I, claims 2-40, an emulsion comprising an oil phase selected from the group consisting of a fatty acid alkyl ester and a triglyceride (there is no enzyme present) wherein the oil phase is a fatty acid alkyl ester and the enzyme reaction is a transesterification in the reply filed on 7/17/09 is acknowledged. The specie election for the choice of an alkyl fatty acid ester or a triglyceride for the emulsion is withdrawn since the prior art discloses an emulsion having both species (see below).

Claims 34-37 and 41-44 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected specie and invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 7/17/09.

Claims 20-33 and 38-40 are presented for examination.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 38-40 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. A single claim that claims both an product or apparatus and the method steps of using the product or apparatus should be rejected under 35 U.S.C. § 101 based on the theory that the

claim is directed to neither a "process" nor a "machine," but rather embraces or overlaps two different statutory classes of invention set forth in 35 U.S.C. § 101, which is drafted so as to set forth the statutory classes of invention in the alternative only. *Ex parte Lyell,*17 USPQ2d 1548 (Bd. Pat. App. & Inter. 1990) at 1551. See M.P.E.P. §2173.05(p). In this case, the claims are drawn to a an emulsion and method steps of using the same ("is used in a enzyme-catalyzed reaction"). A claim can not be drawn to two different classes of statutory classes.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 38-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 38 is rejected because the claim is simultaneously drawn to a product and a method of using a product. It is unclear if the claim is a product claim or a method claim.

Claims 39 and 40 are rejected because they are dependent claims that do not overcome the deficiencies of the rejected independent claim from which they depend.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The claims are drawn to an o/w emulsion comprising water, an emulsifier and an oil phase wherein the emulsion is produced by a PIT process and has a droplet size of 50 to 400 nm. The composition of the oil phase comprises compounds selected from fatty acids alkyl ester and triglycerides. The emulsion comprises an emulsifier of formula I. The oil phase is present in an amount of about 10 to 80 wt.%. The water phase is present in an amount of about 20 to 90 wt.%, 30 to 80 wt.% or 30 to 70 wt.%. The emulsifier can be a system comprising a hydrophilic emulsifier with an HLB of 8 to 18 and an hydrophobic emulsifier. The ratio of the hydrophilic to the hydrophobic emulsifier is 90:10 or 10:90. The emulsifier is present in an amount of about 1 to 25 wt.%, 5 to 20 wt.% or 5 to 15 wt.%. The emulsifier is used for enzyme catalyzed transesterification that produces s cosmetic, pharmaceutical or fine chemical that comprises a carotinoid, a sterol-containing oil and/or vitamin E.

Claims 20-23, 25-33 and 38-40 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Molitor et al. (DE 19923785, English translation provided by the EPO and the Derwent abstract thereof).

Molitor discloses an oil-in-water elusion comprising water, emulsifiers and an oil phase prepared by phase inversion temperature process. The droplet size of the emulsion is 50 to 400 nm (instant claim 20) and the emulsion comprises fatty acid methyl esters and/or plant-derived triglycerides (instant claim 21; translation, description, page 3/10, lines 3-10 and claim 1). The water content is

20 to 90 wt.% or 30 to 80 wt% (translation, claim 3), thus anticipating instant claims 25 and 26, respectively. Molitor also teaches that the water content is from 30 to 70 wt.%, which anticipates instant claim 27 since it is a specie that falls within said claimed ranges. Molitor discloses that the oil phase content is 10 to 80 wt. % (claim 4 of the translation), thus anticipating instant claim 23. The emulsifier comprises a combination of a hydrophilic emulsifier with a HLB of 8-18 and a hydrophobic emulsifier, as in instant claim 28 (translation, description p 6/10 lines 26-31 and claim 8 of the translation). The emulsifier is present in an amount of 1-25 wt.%, 5 to 20 wt.% ant 5 to 15 wt.% (translation claim 10), thus anticipating in claims 31, 32 and 33, respectively. Molitor teaches the ratio of the hydrophilic emulsifier to the hydrophobic emulsifier is 10:90 to 90:10 (translation, description, page 8/10, lines 2-3 and claim 9), as in instant claims 29 and 30.

The fatty acid methyl ester can be methyl stearate or methyl palmitate, thus anticipating the structure of formula I of claim 22 wherein R^1 is 16 or 18 carbons and R^2 is methyl. The reference is silent regarding the emulsifying characteristics of the fatty acid alkyl ester. However, the cited prior art meets this limitation because a compound and its properties are inseparable. In this case, burden is shifted to the Applicant to distinguish the instant invention over the prior art. It is noted that In re Best (195 USPQ 430) and In re Fitzgerald (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe inherently includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter shown to be in

the prior art does not possess characteristic relied on" (205 USPQ 594, second column, first full paragraph).

Claims 38-40 are drawn to an intended use that carriers little patentable weight since the intended use of the claimed invention does not result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. Since the prior art structure is capable of performing the intended use, then it meets the claims.

Claim Rejections - 35 USC § 102/103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 20-33 and 38-40 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Molitor et al. (DE 19923785, English translation by EPO and the Derwent abstract thereof).

The disclosure by Molitor is discussed supra. Molitor teaches that the oil content is from 30 to 60 wt.% (claim 3 of the translation).

Molitor does not teach the limitations of claim 24 wherein the oil phase is present in an amount of 20 to 50% by weight.

The disclosure by Molitor meets the limitations of claim 24 wherein the oil phase is present in an amount of about 20 to 50 wt.%. The disclosure of 30% (the lower end of the prior art range) is a specie that anticipates the claimed range. The generic disclosure suggests or motivates the specific value, 50 wt.%, which is the upper end of the claimed range. The values between 30 and 50 wt.% are species within the prior art which suggest the same values as claimed.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 20-23, 25 28-32 and 38-40 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 24, 25, 27-29 and 31-32 of copending Application No. 11/816,419. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 24 of '419 is drawn to an o/w emulsion comprising water, one or more emulsifiers and an oil phase wherein the emulsion is prepared by PIT and the droplet size is 50 to 400 nm, as in instant claim 20 and 38-40. Claims 38-40 of the instant application are drawn to an intended use that does not make a structural difference in the claims and thus, carries little patentable weight. Claims 25 and 27 of '419 recite that the oil phase comprises one or more fatty acid alkyl esters, as in instant claim 21 and 22. Claim 28 of '419 is present in about a range of 10 to 80% as in instant claim 23. Claim 29 recites that the oil phase is present in an amount of about 20 to 90% wt.%., as in instant claim 25. Claim 31 of '419 recites that the emulsifier is s system comprising a hydrophobic emulsifier and a hydrophilic emulsifier having an HLB of from 8 to 18, as in instant claim 28. Claim 32 of '419 recites the ratio of the hydrophilic to hydrophobic emulsifiers as in instant claims 29 and 30. Claim 32 of '419 is drawn

to the quantity of emulsifier as in instant claims 31-33. Claims 39-42 of '419 recite intended uses of the emulsion that bear little patentable weight since they do not results in a structural difference in the claimed invention. Thus, the claims have the limitations of claim 24 of '419 and anticipate instant claims 20 and 38-40. Claims 38-40 of the instant application are also drawn to an intended use that does not make a structural difference in the claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSAN HANLEY whose telephone number is (571)272-2508. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sandra Saucier/
Primary Examiner, Art Unit 1651

/Susan Hanley/
Examiner, Art Unit 1651